

FORM PTO-1390 (REV. 10-2003) modified		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTORNEY'S DOCKET NUMBER <b>3033 USOP</b>	
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371				U.S. APPLICATION NO. (If known, see 37 CFR 1.5 <b>10/507044</b>	
INTERNATIONAL APPLICATION NO. <b>PCT/JP03/02783</b>		INTERNATIONAL FILING DATE <b>March 10, 2003</b>		PRIORITY DATE CLAIMED <b>March 11, 2002</b>	
TITLE OF INVENTION <b>REMEDIES FOR SEX HORMONE-DEPENDENT DISEASE</b>					
APPLICANT(S) FOR DO/EO/US <b>Takahito HARA; Masami KUSAKA</b>					
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:					
<ol style="list-style-type: none"> <li>1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a filing under 35 U.S.C. 371.</li> <li>2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a filing under 35 U.S.C. 371.</li> <li>3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</li> <li>4. <input checked="" type="checkbox"/> The US has been elected (Article 31).</li> <li>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input checked="" type="checkbox"/> has been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</li> </ol> </li> <li>6. <input checked="" type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). <ol style="list-style-type: none"> <li>a. <input checked="" type="checkbox"/> is attached hereto.</li> <li>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</li> </ol> </li> <li>7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> have been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</li> <li>d. <input checked="" type="checkbox"/> have not been made and will not be made.</li> </ol> </li> <li>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).</li> <li>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</li> <li>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</li> </ol>					
Items 11 to 20 below concern document(s) or information included:					
<ol style="list-style-type: none"> <li>11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. Cited Reference</li> <li>12. <input checked="" type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</li> <li>13. <input checked="" type="checkbox"/> A preliminary amendment.</li> <li>14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.</li> <li>15. <input type="checkbox"/> A substitute specification.</li> <li>16. <input type="checkbox"/> A power of attorney and/or change of address letter.</li> <li>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.</li> <li>18. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4).</li> <li>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</li> <li>20. <input checked="" type="checkbox"/> Other items or information: <div style="display: flex; justify-content: space-between; margin-top: 5px;"> <div> Itemized Return Postcard; Certificate of Express Mailing;  Cover Page International Application; ISR;  Forms PCT/IB/301, 304, 308 </div> <div> Express Mail Label No. EV 524905883 US  Date of Deposit September 9, 2004 </div> </div> </li> </ol>					

U.S. APPLICATION NO. <b>10/507044</b> <small>U.S. PAT. &amp; TM. OFF. 37 CFR 1.53</small>		INTERNATIONAL APPLICATION NO. <b>PCT/JP03/02783</b>		ATTORNEY'S DOCKET NUMBER <b>3033 USOP</b>	
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21. <input checked="" type="checkbox"/> The following fees are submitted: <b>BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):</b> Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO. .... <b>\$1080.00</b>  International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO ..... <b>\$920.00</b>  International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO ..... <b>\$770.00</b>  International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) ..... <b>\$730.00</b>  International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) ..... <b>\$100.00</b>  <b>ENTER APPROPRIATE BASIC FEE AMOUNT =</b>				<b>CALCULATIONS PTO USE ONLY</b>          <table style="width:100%; border: none;"> <tr> <td style="width:10%; border: none;">\$</td> <td style="width:40%; border: none; text-align: right;"><b>920.00</b></td> <td style="width:50%; border: none;"></td> </tr> </table>		\$	<b>920.00</b>	
\$	<b>920.00</b>							
Surcharge of <b>\$130.00</b> for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				<table style="width:100%; border: none;"> <tr> <td style="width:10%; border: none;">\$</td> <td style="width:40%; border: none; text-align: right;"><b>0</b></td> <td style="width:50%; border: none;"></td> </tr> </table>		\$	<b>0</b>	
\$	<b>0</b>							

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$	
Total claims	33 - 20 =	13	x \$18.00	\$	234.00
Independent claims	15 - 3 =	12	x \$86.00	\$	1,032.00
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$290.00	\$	0
<b>TOTAL OF ABOVE CALCULATIONS =</b>				\$	2,186.00

<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.	\$	0
<b>SUBTOTAL =</b>		
\$ 2,186.00		

Processing fee of <b>\$130.00</b> for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$	0
<b>TOTAL NATIONAL FEE =</b>				\$	2,186.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). <b>\$40.00</b> per property +				\$	40.00
<b>TOTAL FEES ENCLOSED =</b>				\$	2,226.00

	Amount to be refunded:	\$
	charged:	\$

a. ☐ A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.

b. ☒ Please charge my Deposit Account No. 500799 in the amount of \$ 2,226.00 to cover the above fees.  
 A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 500799. A duplicate copy of this sheet is enclosed.

d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

**NOTE:** Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

Mark Chao, PhD, JD  
 Takeda Pharmaceuticals North America, Inc.  
 475 Half Day Road  
 Lincolnshire, IL 60069 USA  
 (847)383-3372 fax (847)383-3409

SIGNATURE  
 Mark Chao, PhD, JD  
 NAME  
 37,293  
 REGISTRATION NUMBER  
 For Customer No. 23,115

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	Based on PCT/JP03/02783	Art Unit:	tba
Filed:	Intl. Filing 10 MARCH 2003	Examiner:	tba
1 <sup>st</sup> Inventor:	HARA, Takahito	Allowed:	
For:	Remedies for Sex Hormone-Dependent Disease	Batch:	
Atty. Dkt. No.	3033 US0P	Paper No.:	

CERTIFICATE OF EXPRESS MAILING UNDER 37 CFR 1.10

USPS EXPRESS MAIL LABEL. No. EV 524905883 US

DATE IN: September 9, 2004

## Itemized Papers/Items:


1. This Certificate and Return Postcard (2 pages)
2. Transmittal Letter for Filing under 35 USC 371 (2 pages X 2)
3. PCT Request (5 pages)
4. Specification - total pages (78 including Claims 1-33(pages 71-76), Abstract (1 page), and Formal Drawing (1)
5. Declaration and Power of Attorney (3 pages)
6. Copies of Forms PCT/IB/301, 304, 308 (4 pages)
7. Copy of Cover Page International Application (WO 03/075958) (1 page)
8. Copy of International Search Report (4 pages)
9. Preliminary Amendment (2 pages)
10. Information Disclosure Statement (1 page), Forms PTO/SB/08A and 08B (2 pages), cited references (6)
11. Executed Assignment (2 pages) and Recordation Cover Sheet (1 page X 2)

The undersigned hereby certifies that the above itemized papers are together being deposited with the Express Mail Post Office to Addressee service of the United States Postal Service (USPS) in an envelope with sufficient postage, having the USPS Express Mail Label No. shown above, and addressed to:

MAIL STOP PCT  
P.O. BOX 1450  
Commissioner for Patents  
Alexandria, VA 22313-1450

on this date, 9/9/04

Dated: 9/9/04

  
Gail L. Winokur

Takeda Pharmaceuticals North America, Inc.  
Intellectual Property Department  
475 Half Day Road  
Lincolnshire, IL 60069 USA

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